Canyon-I-Pilot Trial a dose-ranging study of bolus-only Desirudin in patients undergoing PCI

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The aim of this study is to find out if a percutaneous angioplasty can be carried out safely in patients who received a therapeutic dose of Desirudin (Revasc®) before the operation.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON35683

Source
ToetsingOnline

Brief title
CANYON-PCI pilot study

Condition

- Coronary artery disorders

Synonym
narrowing of the coronary arteries; chest pain

Research involving
Human

Sponsors and support

Primary sponsor: Canyon Pharmaceuticals Inc.
Source(s) of monetary or material Support: de sponsor

Intervention

Keyword: Desirudin, direct thrombin inhibitor, PCI

Outcome measures

Primary outcome

The primary objective of this trial is to evaluate the change in ultrasensitive troponin within 6-8 hours, 14-16 hours, and 22-24 hours following the index procedure, as a surrogate marker for peri-procedural ischemic events.

Secondary outcome

The secondary objectives are to compare:

• the combined safety and the preliminary efficacy towards prevention of ischemic events and major bleeding of two doses of Revasc® (Desirudin 30mg, 45mg), as compared to unfractionated heparin (UFH) and Bivalirudin, in addition to a standard dual antiplatelet regimen, in the setting of elective low to medium risk Percutaneous Coronary Intervention (PCI)

• the individual components of the primary endpoint, and of other major clinical endpoints;

• the safety of the treatments plus dual antiplatelet therapy, particularly with respect to bleeding complications;

• clinical signs of thrombosis;

• the coagulation profile of two different doses of Desirudin in addition to a standard dual antiplatelet regimen in the setting of elective PCI.

• The differential effect of different anticoagulation regimens on neutrophil activation, myeloperoxidase release and systemic inflammation following PCI.

Study description

Background summary

During percutaneous angioplasty, the blood vessel wall can become damaged. This damage can give rise to formation of a blood plug or clot. A blood plug or clot is caused by components in the blood such as thrombin and blood platelets. This blood clot can disrupt the flow of blood in your coronary artery and can even give rise to a complete blockage of the blood vessel, which will result in a heart attack. In order to prevent this you will receive medicines (aspirin and clopidogrel/plavix) which ensure that the effect of thrombin and blood platelets is inhibited. In addition to this an anticoagulant such as heparin shall be given during the procedure.

For more than 50 years heparin has been the most important medicine for inhibiting thrombin. Despite its unmistakable advantages, this product also has many shortcomings: finding the correct dose is often difficult, there is a risk of antibodies being produced. Other new medicines with a similar effect are now being developed.
Desirudin (Revasc®) is a new anticoagulant. Desirudin (Revasc®) is a medicine which ensures that the effect of thrombin is inhibited. In clinical trials it has been demonstrated that Desirudin (Revasc®) has a good anticoagulant effect and it has proved successful in patients who had to undergo a hip or knee operation.

Study objective

The aim of this study is to find out if a percutaneous angioplasty can be carried out safely in patients who received a therapeutic dose of Desirudin (Revasc®) before the operation.

Study design

The study is a randomized open label study. Participation in the study will last for about 1 month.
In the week before the planned PCI procedure a screening visit will be done during wghich the patient will be randomized to one of the four treatment groups.
During the procedure until discharge coagulation parameters will be performed.
Thirty days after the procedure the patient will ne contacted by phone for follow-up.

Intervention

Patients who participate in this study will receive 1 of the 4 treatment groups administered before the PCI procedure.

Study burden and risks

Physical examination is done twice
Blood will be drawn 12 times, approximately 300 mls in total
Three ECgs will be recorded.
A pregnancy test will be done for women.

Contacts

Public
Canyon Pharmaceuticals Inc.

Executive Plaza One Suite 400
11350 McCormick Road, Hunt Valley, MD 21031
USA
Scientific
Canyon Pharmaceuticals Inc.

Executive Plaza One Suite 400
11350 McCormick Road, Hunt Valley, MD 21031
USA

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

The patient is at least 18 years old;
The patient is due to undergo an elective PCI on one or multiple lesions in the coronary vessel(s)
The patient provided written informed consent

Exclusion criteria

The patient is not a candidate for PCI
The patient experienced an acute Myocardial Infarction within previous 4 weeks.
The patient has an increased bleeding risk
Hemodynamic instability
Severe hypertension

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-09-2009
Enrollment:	50
Type:	Anticipated

Medical products/devices used

Product type:	Medicine

Brand name:	Bivalirudin
Generic name:	Angiox
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Desirudin
Generic name:	Revasc
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Heparin
Generic name:	Heparin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	15-07-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-01-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2009-010903-98-NL
CCMO	NL28449.078.09